

**Remarks**

In response to the Office Action mailed April 13, 2007, Applicants submit the following remarks. The statutory deadline for filing a response is August 13, 2007. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fee. Therefore, Applicants believe that this response is being timely filed. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-754.201.

By the above amendments, the specification has been amended to incorporate the language recited in claims 24, 34 and 35 as originally filed. The amendment is clearly supported by the disclosure, including the claims, as originally filed. Entry of the amendment to the specification is therefore proper. Such action is respectfully requested.

The claims were amended to recite that the method provides uniformity of coating from microprotrusion to microprotrusion. This amendment is supported throughout the specification as originally filed. See for example paragraphs [0060], [0065] and [0070]. Accordingly, entry of the amendments is proper and respectfully requested.

*Claim Rejections – 35 USC § 112*

Claims 22, 34 and 35 were rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement.

At the outset, it is noted that it is well-settled that the original claims are part of the original application disclosure. The allegedly objectionable language was present in the claims as originally filed. Accordingly, rejection of the claims for lack of enablement is not proper. However, in order to expedite prosecution of the application, Applicants have emended the specification to recite language provided in the original claims.

Thus, the rejection of Claims 22, 34 and 35 under 35 U.S.C. 112, first paragraph should be withdrawn. Such favorable action is respectfully requested.

Claim 23 was rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 has been revised consistent with the suggestion kindly provided in the Office Action. Accordingly, the rejection is believed to be rendered moot. Thus withdrawal of the rejection is respectfully requested.

*Claim Rejections – 35 USC § 103*

Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Szumski et al (3,470,011). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Palmer (6,537,242). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Powell (6,589,202). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 96/10630. Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ginaven et al. (5,457,041). Claims 18-24, 29-35 and 47 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Cormier et al. (US2002/010292). These rejections are traversed for at least the following reasons.

The rejections under 35 U.S.C. 103(a) raise similar issues and are therefore addressed as a group.

As defined by present Claim 18, the subject invention relates to a method of making a device for transdermally delivering a pharmacologically active agent, the method comprising: providing a member having a plurality of stratum corneum-piercing microprotrusions; applying an aqueous solution of the pharmacologically active agent onto the member; and drying said applied aqueous solution to form a dry agent-containing coating on said member. The agent is sufficiently potent to be therapeutically effective when administered in an amount of less than about 1 mg, said agent having an aqueous solubility at about 25°C of greater than about 50 mg/ml and said aqueous solution having a viscosity at about 25°C less than about 500 centipoises. And, the method provides uniformity of coating from microprotrusion to microprotrusion.

None of the references relied upon in the Office Action provide the requisite guidance to achieve the claimed method for preparing a member having a plurality of stratum corneum-piercing microprotrusions having a dry agent-containing coating, wherein the method provides uniformity of coating from microprotrusion to

microprotrusion. Thus, none of the references, taken alone or in combination, suggest the presently claimed method.

Accordingly withdrawal of the rejections under 35 U.S.C. 103(a) based on Szumski et al, Palmer, Powell, WO 96/10630, Ginaven et al., and Cormier et al. is respectfully requested.

**Provisional Double Patenting**

Claims 18-24, 29-35 and 47 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 54-64 of copending U.S. Application No. 11/034,891. Claims 18-24, 29-35 and 47 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 28-54 of copending U.S. Application No. 10/127,108, over claims 21-39 of copending U.S. Application No. 10/674,626, over claims 10-13 of copending U.S. Application No. 10/972,231, claims 33-38 of copending U.S. Application No. 11/201,625, claims 32-34 of copending U.S. Application No. 11/206,698 and claims 30-35 of copending U.S. Patent Application No. 11/355,856.

Applicants, respectfully request that the double patenting rejections be stayed in abeyance until the subject application is indicated to be otherwise allowable.

## CONCLUSION

Applicants believe that, for the reasons explained above, all of the pending claims are in condition for allowance and such favorable action is respectfully requested. The one-month extended deadline for filing a response is August 13, 2007. Applicants submit herewith a one-month Petition for Extension of Time and the appropriate fee. Therefore, Applicants believe that this response is being timely filed. Applicants believe that the fees submitted herewith are sufficient. However, in the event that Applicants are incorrect in their assumption, please charge any necessary fee to Deposit Account No. 23-2415, referencing Docket No. 33392-754.201.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 350-2337.

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Respectfully submitted,

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